

REMARKS

Claims 1-6, 8-11 and 13-24 are pending. Claims 2-6, 8-9, and 13-18 are withdrawn from consideration. Applicant reserves the right to file one or more divisional application(s) on the non-elected subject matter. As to method claim 16, drawn to a non-elected invention, applicant respectfully requests the rejoinder, pursuant to the *Ochiai/Brouwer* guidelines.

Rejection under 35 U.S.C. § 112, First Paragraph

The Office maintains the rejection of claims 1, 10-11, and 19-24 as being “containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention”. Office action, paragraph 4. In support of this rejection, the Office states:

The support for the 31-kD protein only comes from evidence not in the specification as originally filed. The specification does not have any 2-D gel or labeled protein on the gel that indicates that BLCA-6 is 22-kD found in Table 1. The specification contains only two figures which do not indicate the MW of any of the BLCA proteins. Without the 2-D gels one skill in the art would not know that the BLCA-6 protein is 31-kD or supposed to be 31-kD. Although the response states that this is an inherent property of the protein, without the gels one can not know what the MW is supposed to be except 22-kD.

Id. Applicant respectfully traverses this rejection.

The specification describes procedures for extracting nuclear matrix proteins from tumor and normal bladder tissue samples and separating them by high resolution two-dimensional gel electrophoresis. See the specification, for example, at pages 30-32. By following these procedures, a skilled artisan would obtain six proteins that are present in all of the tumor samples and absent in the normal samples, including one protein having an MW and an isoelectric point (pI) equal to about 31-kD and 8.00, respectively. See Declaration under 37 C.F.R. § 1.132 filed on December 23, 2003, at paragraphs 8 and 9 and in Appendix D. Thus, the specification necessarily discloses a protein having a pI of about 8.00 and an MW of about 31 kD.

The aforementioned declaration, in paragraph 5, attests that the BLCA-6 protein disclosed in the specification is the same as that described in Getzenberg *et al.*, *Cancer Research* 56:1690-94, 1996. This attestation comports with the similarities apparent between the text of Getzenberg *et al.* (1996) and the specification. The Getzenberg paper discloses that BLCA-6 has an MW of 31-kD and a pI of 8.00 (page 692), and the declaration confirms that the correct MW of BLCA-6 is 31 kD (paragraph 8). Thus, the evidence of record compels the conclusion that the protein disclosed by the specification, having a pI of about 8.00 and an MW of about 31 kD, indeed is BLCA-6.

Conversely, the record is devoid of any evidence that a skilled person, following the procedures set forth in the specification, would obtain a protein having an MW other than 31 kD but otherwise possessing the same properties associated with BLCA-6. In the absence of such evidence, the examiner has no basis for questioning the specification in this regard.

In light of the above remarks, Applicant respectfully requests withdrawal of this rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph

In paragraph 5, the Office maintains the rejection of claims 1, 10-11, and 19-24 as “containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.” In this regard the Office states:

There is no indication in the specification as originally filed to indicate that BLCA-6 is 31-kD. Although SEQ ID NO:4 is associated with the 22-kD protein, BLCA-6 in the specification, there is no evidence that the 31-kD protein has SEQ ID NO:4. In addition, even if the 31-kD protein has SEQ ID NO:4, this does not give evidence that the 22-kD protein should be BLCA-6 because the 31-kD protein that has SEQ ID NO:4 could also be processed to a 22-kD protein in the specification that has SEQ ID NO:4....Although there is an indication (in the prior art and the declaration of Getzenberg) that the molecular weight is incorrect, there is nothing from the specification as filed to indicate that this is true. One could also equally argue that the pI or the sequence is incorrect.

Id. Applicant respectfully traverses this rejection.

Application Serial No. 09/866,927:

As mentioned above, the specification inherently discloses a protein having a pI of about 8.00 and an MW of about 31 kD.

The specification expressly teaches that BLCA-6 has SEQ ID NO:4. While the specification erroneously specifies the MW of BLCA-6 as 22-kD, the foregoing evidence and arguments overwhelmingly support that the correct MW of BLCA-6 is 31-kD. A “specification...must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). Without presenting any evidence that the pI or the sequence of BLCA-6 is incorrect, the Office has failed to satisfy its initial burden of challenging a presumptively correct assertion of utility in the disclosure.

For these reasons, Applicant respectfully requests withdrawal of this rejection.

Priority

The Office has granted the instant application a priority date of May 30, 2001 on the basis of its consideration that the specification contains new matter and that the pending claims are non-enabling. Applicant respectfully disagrees with the Office on this issue.

Based on the inherent property of the BLCA-6 protein and the above-mentioned arguments, Applicant requests that the Office reconsider the priority date of the present application as November 3, 1995.

Rejection under 35 U.S.C. § 102(b)

The Office maintains the rejection of claims 1, 10-11, 20 and 24 as being anticipated by Getzenberg *et al.* (1996). Applicant submits that Getzenberg *et al.* (1996) is not a patent-defeating reference because it has an effective prior art date of April 1996, which is after the effective priority date of the present application, that is, November 3, 1995. Accordingly, Applicant respectfully requests withdrawal of this rejection.

Application Serial No. 09/866,927:

Rejection under 35 U.S.C. § 103

The Office maintains the rejection of claims 1, 10-11, and 19-24, as being unpatentable over Getzenberg *et al.* (1996), as applied to claims 1, 10-11, 20 and 24, and further in view of Coffey *et al.* (U.S. Patent No. 6,030,793). Since Getzenberg *et al.* (1996) is not prior art to the instant claims for the reasons set forth above, a *prima facie* case of obviousness is not possible. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date

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